

## **REMARKS**

### **The Amendments**

Claim 1 is amended to clarify the active nature of the composition in accordance with the disclosure at page 10, lines 8-14, for example. Claims 4 and 5 are amended to provide chemical names for the alphanumeric identifiers. A document showing support for the synonymous nature of the terms is filed herewith.

Applicants reserve the right to file one or more continuing and/or divisional applications directed to any subject matter disclosed in the application which has been canceled by any of the above amendments.

### **The Rejection under 35 U.S.C. §112, second paragraph**

The rejection of claims 1-8 and 35-37 under 35 U.S.C. §112, second paragraph, is believed to be rendered moot by the above amendments. The MEN-11420 recitation is deleted and the alphanumeric compound designators are replaced by compound names, where possible. The other alphanumeric names are known compounds and no disclaimer of them is made. The amendment is merely made to advance prosecution. The rejection should thus be withdrawn.

### **The Obviousness-type Double Patenting Rejection**

The obviousness-type double patenting rejection of claims 1-8 and 36 over claim 9 of Meissner (U.S. Patent No. 6,706,726) is overcome by the terminal disclaimer filed herewith.

### **The Rejection under 35 U.S.C. §103**

The rejection of claims 1-8 and 35-37 under 35 U.S.C. §103, as being obvious over

Meissner (U.S. Patent No. 6,706,726) and Leroy (Expert Opinion), is respectfully traversed.

Meissner discloses compounds of its formula I as anticholinergics, particularly for treating asthma or COPD (chronic obstructive pulmonary disease). Meissner does not provide any suggestion of a composition of such compounds together with an NK<sub>1</sub> receptor antagonist.

Leroy teaches that tachykinins are involved in the pathology of respiratory diseases and airway allergy but the teachings as to use of NK<sub>1</sub> receptor antagonists to treat any particular respiratory disease in Leroy are mixed and, at best speculative. See particularly the first full paragraph on page 742, wherein, Leroy states that “Early results with NK<sub>1r</sub> antagonists have been disappointing.” Further, Leroy indicates that the NK<sub>1</sub> receptor antagonist SR-140333 was not effective on allergen-induced early and late asthmatic responses (EAR and LAR). It was found only to reduce inflammation and hyper-reactivity (AHR). Further, the teaching regarding FK-888 does not teach its effectiveness for treating bronchoconstriction of allergic asthma, as stated in the Office action. To the contrary, Leroy teaches that FK-888 “did not affect the acute response” and only had some effect when used together with an NK<sub>2</sub> antagonist (paragraph bridging the columns on page 742).

As a whole, applicants disagree with the statement and overall conclusion in the Office action that Leroy provides a reasonable expectation of successfully using an NK<sub>1</sub> receptor antagonist to treat a disease of the respiratory tract, such as asthma or COPD. Leroy provides merely some speculation that some NK<sub>1</sub> receptor antagonists might have some effects on certain aspects of allergic response connected with asthma. But, as a whole, Leroy is contrary to providing a reasonable expectation that NK<sub>1</sub> receptor antagonists were useful for treating respiratory diseases. Leroy points more to the failings of NK<sub>1</sub> receptor antagonists than their successes and thus, as a whole, fails to provide a reasonable

expectation of success in using these compounds to treat a respiratory disease.

Further, both Meissner and Leroy are silent as to the combined effect of an anticholinergic and NK<sub>1</sub> receptor antagonist. There is no suggestion that the combined effect of these compounds would be reasonably expected to succeed for treating a respiratory disease or for any other reason.

Additionally, Leroy clearly provides no suggestion that NK<sub>1</sub> receptor antagonists would be useful for treating COPD (particularly in conjunction with an anticholinergic). As discussed above, Leroy's teachings regarding NK<sub>1</sub> receptor antagonists are mixed and speculative, at best, as to their use in treating allergic asthma. However, COPD is a non-inflammatory and non-allergic disease. Thus, one of ordinary skill in the art would, in no way, have been motivated from Leroy's teaching regarding anti-allergic and anti-inflammatory effects to use NK<sub>1</sub> receptor antagonists to treat COPD.

For all of the above reasons, applicants respectfully urge that the instant facts are not in line with the citation in the Office action to In re Kerkhoven. The prior art of Leroy does not suggest – with a reasonable expectation of success – the use of NK<sub>1</sub> receptor antagonists to treat a respiratory disease. And certainly Leroy does not suggest the use of NK<sub>1</sub> receptor antagonists to treat COPD. Thus, there is no motivation to combine NK<sub>1</sub> receptor antagonists with the anticholinergics of Meissner for such treatments. Nor is any other reason for their combination in the claimed compositions provided on the record.

Thus, the combined teachings of the prior art fail to render the claimed invention obvious to one of ordinary skill in the art and the rejection under 35 U.S.C. §103 should be withdrawn.

It is submitted that the claims are in condition for allowance. However, the Examiner

is kindly invited to contact the undersigned to discuss any unresolved matters. Because the elected species are believed to be allowable, examination should extend to the non-elected species of the withdrawn claims. The arguments for patentability apply equally thereto.

No fee, other than the 2-Month Extension of Time being paid herewith, is believed to be due with this Reply. However, the Commissioner is hereby authorized to charge any additional fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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